

**Notice of Allowability**

Application No.

09/841,188

Examiner

Khatol S Shahnan-Shah

Applicant(s)

WARMINGTON ET AL.

Art Unit

1645

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to supplemental amendmend of 3/5/04.
2. ☒ The allowed claim(s) is/are 18-37 renumbered 1-20 respectively.
3. ☐ The drawings filed on \_\_\_\_\_ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |   |  |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)  | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 2. <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                                 | 6. <input type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No./Mail Date _____ | 7. <input type="checkbox"/> Examiner's Amendment/Comment                               |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material          | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance   |
|   | 9. <input type="checkbox"/> Other _____.   |

***Attachment to Notice of Allowance***

1. Applicants' amendment and response, received 05 March 2004 are acknowledged. Claims 18, 32, 35 and 37 have been amended.
2. Claims 18-37 are pending and under consideration.

***Rejections Withdrawn***

3. Rejections of claims 18-34 and 37 under 35 U.S.C. 102 (b) made in paragraphs 14 and 15 of the office action mailed 7/09/2003 are withdrawn in view of applicants' amendments.
4. Rejections of claims 35-36 under 35 U.S.C. 103 (a) made in paragraph 16 of the office action mailed 7/09/2003 is withdrawn in view of applicants' amendments.

***Reason for Allowance***

5. Claims 18-37 are allowed. Claims are renumbered 1-20 respectively.

The following is an examiner's statement of reasons for allowance:

The claims are drawn to a method of diagnosing *Candida* infection, comprising the steps of:

- a) obtaining a biological sample from a subject at risk of, or suspected to be suffering from *Candida* infection;
- b) preparing a composition comprising antigen consisting of a soluble cytoplasmic antigen preparation which is mannose, depleted and which consists essentially of *Candida* antigens of molecular weights 55kDa, 30kDa and 20kDa;
- c) contacting said antigen with said biological sample; and

d) using a detection system to determine if antibodies from the biological sample are bound to said antigen composition.

In the previous office action dated 7/09/2003 claims 18-34 and 37 were rejected under 35 U.S.C. 102 (b) as being anticipated by Buckley et al. and claims 35-36 were rejected under 35 U.S.C. 103 (a) as being unpatentable over Buckley et al. in view of Miyada et al.

The rejections of claims 18-34 and 37 under 35 U.S.C. 102 (b), and 35-36 under 35 U.S.C. 103 (a) based on Buckley et al. are hereby withdrawn in view of the amendments to claims 18, 32, 35 and 37 requiring that the composition consisting of a soluble cytoplasmic antigen preparation which is mannose, depleted and which consists essentially of *Candida* antigens of molecular weights 55kDa, 30kDa and 20kDa. Buckley et al. teach 3 *Candida* cytoplasmic antigens extracted from mycelial form of *Candida* having molecular weights of 120-135kDa, 48-52 kDa and 35-38 kDa but fails to teach a composition which consists essentially of *Candida* antigens of molecular weights 55kDa, 30kDa and 20kDa. The prior art fails to teach the claimed invention.

6. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

#### ***Conclusion***

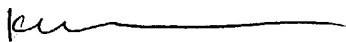
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol S Shannan-Shah whose telephone number is (571)-272-0863. The examiner can normally be reached on 7:30am-4 pm.

Art Unit: 1645

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F Smith can be reached on (571)-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

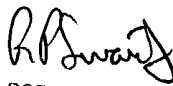


Khatol Shahnan-Shah, BS, Pharm, MS

Biotechnology Patent Examiner

Art Unit 1645

March 30, 2004



RODNEY P. SWARTZ, PH.D  
PRIMARY EXAMINER